

*A1*  
1. (Amended) A method of treating or prophylaxis of a disorder ameliorated by the inhibition of serotonin reuptake at 5-HT<sub>2</sub> receptors and/or the inhibition of dopamine reuptake at dopamine D<sub>2</sub> receptors in a patient which comprises administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a ziprasidone metabolite, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof.

*A2*  
3. (Amended) A method of treating or prophylaxis of a neuroleptic disorder in a patient which comprises administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a ziprasidone metabolite, or a pharmaceutically acceptable salt, solvate, hydrate, or clathrate thereof.

#### REMARKS

Claims 1-15 are pending in this application. Claims 16-49 have been canceled further to the Restriction Requirement mailed June 25, 2001 without prejudice to Applicants' right to pursue the subject matter they recite in one or more continuation, divisional, or continuation-in-part applications. The title has been amended as shown in Appendix A, attached hereto, to more accurately reflect the subject matter of the pending claims. Claims 1 and 3 have been amended as shown in Appendix A. No new matter has been added.

#### I. The Rejection Under 35 U.S.C. § 112 Should be Withdrawn

On pages 2-3 of the Office Action, claims 1-15 are rejected under the second paragraph of 35 U.S.C. § 112 as allegedly indefinite. In particular, the term "prevented" is objected to because examples of how and when to prevent disorders are allegedly not provided, and because the "degree of prevention" is allegedly unclear. Applicants respectfully disagree. However, because it is suggested on page 3 of the Office Action that this rejection will be withdrawn if the term "prevented" is replaced with "prophylaxis," claims 1 and 3 have been amended accordingly to expedite their allowance.

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II. The Rejection Under 35 U.S.C. § 102 Should be Withdrawn

On page 3 of the Office Action, claims 1-4 and 6-9 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by what appears to be a Pfizer publication entitled “GEODON™ (ziprasidone HCl)” (“Geodon”). This rejection is respectfully traversed.

The Geodon publication is dated April 2001. Geodon, page 20. This application was filed over a year earlier, on March 17, 2000, and claims priority to U.S. provisional application 60/127,939, which was filed April 6, 1999. Geodon is, therefore, not prior art to this application. *See, e.g.*, 35 U.S.C. § 102(a), (b). For this reason, Applicants respectfully request that the rejection of claims 1-4 and 6-9 over Geodon be withdrawn.

III. The Rejection Under 35 U.S.C. § 103 Should be Withdrawn

On pages 3-5 of the Office Action, claims 5 and 10-15 are rejected under 35 U.S.C. § 103 as allegedly obvious over Geodon in view of Prakash *et al.*, Drug. Met. Disp. 25:206-218 (1997) (“Prakash”). This rejection is respectfully traversed.

In order to properly determine a *prima facie* case of obviousness, an Examiner “must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” Manual of Patent Examining Procedure § 2142 (8<sup>th</sup> ed., August 2001). This is important, as “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” *Id.* Three basic criteria must then be met: first, there must be some suggestion or motivation to modify or combine the cited references; second, there must be a reasonable expectation of success; and third, the prior art references must teach or suggest all the claim limitations. *Id.* at § 2143. With regard to the first criterion, it is important to recognize that the “mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” *Id.* at 2143.01 (emphasis in the original) (citing *In re Mills*, 916 F.3d 680 (Fed. Cir. 1990)).

Because the rejection under § 103 is based on the combination of Geodon and Prakash, it stands to reason that Prakash alone cannot satisfy the requirements of § 103. Yet, as discussed above, Geodon is not prior art to this application. Therefore, Applicants respectfully submit that this rejection cannot be made, and request that it be withdrawn.

Conclusion

All of the claims are believed to be in condition for allowance. Should the Examiner disagree, Applicants respectfully request a telephonic or personal interview to address any remaining issues.

No fee is believed to be due for this submission. However, if any fees are necessary for the entry of this submission or to avoid abandonment of this application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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